ETHICON, INC.
a Johnson & Johnson company

Document Name (#): PR602-003
Revision: 7

Company Procedure for
Medical Device Risk Management Plan

Revision History for (PR602-003)

Revision #	Summary of Change	Change Order #	Originator
7	Complete Re-write to better align to ISO 14971: 2000 Standard	CO-0005527	R. McIntyre

EXHIBIT

"HH"

1 Purpose

To provide a process and a plan for Medical Device Risk Management that includes components of the following activities:

- Risk Analysis
- Risk Evaluation
- Risk Control
- Post Production Information

This procedure is established in accordance with part 7.3 of the ETHICON Franchise Quality Manual (PL-0000001).

2 Scope

This procedure applies to:
1. All Business Units governed by ETHICON Quality Systems at the following locations:

- Somerville, New Jersey (NJ), United States
- Cornelia, Georgia (GA), United States
- San Angelo, Texas (TX), United States
- San Lorenzo, Puerto Rico (PR)
- Juarez, Chihuahua, Mexico (MX)

2. All Medical Devices developed and maintained under the auspices of an internal Design Control Process as defined in PR800-011 (New Product Design) and PR800-012 (Design Change Control) most current versions. Components provided by ETHICON to another company for the other company's device(s) are governed by either the other company's risk management processes or PR602-003, as agreed upon between the two companies. Products that are designed and/or developed by an approved supplier can be governed by the supplier's risk management process, if an ETHICON assessment deems it appropriate. In all other cases the risk management process is governed by PR602-003.

3. This plan covers the entire product life cycle for any given, applicable product.

Note: This procedure does not apply to legacy products (see definition in definition section) unless one or both of the following two criteria are met: A design change occurs that requires design validation and/or an unanticipated critical failure mode occurs.

References:

- ISO 14971:2000/Amd.1:2003: "Medical Devices - Application of Risk Management to Medical Devices, Rationale for Requirements"
- ISO 14971:2000: "Medical Devices - Application of Risk Management to Medical Devices
- ISO 13485: 2003: "quality Systems- Medical Devices- Particular requirements for the application of ISO 9001."
- U.S. Food and Drug Administration (FDA) Quality System Requirements (QSR): 21 CFR 820.30
- The ISO 14971 Essentials; 1st Edition: "A Practical handbook for implementing the ISO 14971 Standards for medical devices. "; Canadian Standards Association, ISBN 1-55397-158-2
- IEC 60601-1-4 (edition 1.1 2000-04), "Medical Electrical Equipment-Part 1: General Requirements for Safety, Part 4:Programmable Electrical Medical System."
- BS EN 12442-1 "Animal Tissues And Their Derivatives Utilized In The Manufacture Of Medical Devices - Part 1: Analysis and Management Of Risk."
- European Medical Device Directive (MDD 93/42)

3 Definitions, Acronyms and Abbreviations (An "*" by the term denotes the term is defined as per ISO 14971-2000)

Term	Description
ALARP*	As low as reasonably practicable.
Critical Failure Mode	Any Failure Mode that has a hazard associated with it and the severity of harm emanating from the hazard is assessed at level 9 or 10 (Note: by definition, all hazards are a potential source of harm).
Unanticipated Critical Failure Mode:	Any failure mode that is found after launch of a product and that was not identified as part of the risk analysis activities and that is associated with a hazard, where the severity of harm emanating from the hazard is assessed at severity level 9 or 10. Or: 2. Any failure mode that was identified during the risk analysis activities, but for which the severity of the harm emanating from the hazard was underestimated, and where subsequent post launch experience indicates the actual severity is at level 9 or 10.
Harm*	Physical injury or damage to the health of people.
Hazard*	Potential source of harm.
Hazardous situation*	Circumstances in which people, property or the environment are exposed to one or more hazard(s).
Intended use/Intended purpose*	Use of a product, process or service in accordance with the specifications, instructions and information provided by the manufacturer
Legacy Devices	Devices released under a Risk Management program that pre-dates version 7 of this procedure.
Preliminary Hazard Identification	The preliminary Hazard Identification listing (see Harms/Hazard summary Table on the Risk Management Report Template) with Harm, Severity of Harm and Hazards fields completed and populated. As the project progresses, the list will most likely evolve. This preliminary analysis may be used as design input accordingly.
Product Life Cycle Phases	The four stages that a product goes through from development to obsolescence: Introduction, Growth, Maturity, Decline.
Product Development Phases	Phases of the Ethicon product development process: Discovery, Planning, Development.
Manufacturer*	Natural or legal person with responsibility for the design, manufacture, packaging or labeling of a medical device, assembling a system, or adapting a medical device before it is placed on the market and/or put into service, regardless of whether those operations are carried out by that person himself or on their behalf by a third party.
Medical Device*	Any instrument, apparatus, appliance, material or other articles, whether used alone or in combination, including the

Term	Description
	software necessary for its proper application, intended by the manufacture to be used for human beings for the purpose of: • diagnosis, prevention, monitoring, treatment or alleviation of disease • Diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or handicap • Investigation, replacement or modification of the anatomy or of a physiological process or • control of conception and which does not achieve its principle intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means.
Objective Evidence*	Information that can be proven true based on facts obtained through observation, measurement, test or other means.
Options Analysis	A review of options available to reduce or control risk (see Appendix III for more information).
Product Quality Plan (PQP)	A document which references or includes the important quality elements & controls for a given product or product family.
Record*	Document that furnishes objective evidence of activities performed or results achieved.
Residual Risk*	The risk that remains after protective measures have been taken.
Residual Risk (Overall)	The risk that remains after protective measures have been taken and which is determined by looking at the combined impact of all individual residual risks. It is possible that overall residual risk can exceed the set criteria for acceptance even if the individual risks do not. (May be abbreviated as **ORR**)
Risk*	Combination of the probability of occurrence of harm and the severity of that harm.
Risk Analysis*	Systematic use of available information to identify hazards and to estimate the risk.
Risk Analysis Tool	As per annex F of ISO 14971: Any technique used for probabilistic safety analysis of a device. E.g.: Fault Tree analysis (FTA) or Failure Modes Effects Analysis (FMEA). Such tools may be complimentary in nature and more than one may be used in a Risk Management Plan, depending on the nature of the device.
Risk Acceptability Criteria	The criteria by which either individual and/or overall risks and/or residual risks are accepted as needing no further reduction.
Risk Assessment*	Overall process comprising a risk analysis and a risk

Term	Description
	evaluation.
Risk Benefit Analysis (RBA)	An analysis that contains information about standards of care for a given type of procedure, patient population affected, data regarding expected or baseline mortality or morbidity, review of other available or common treatment modalities that relate to the same procedure and population of patients affected. These standards and data will be reviewed in relation to those data available about the device or accessory in question for the purpose of comparing relative risks vs. relative benefits of the device.
Risk Benefit Analysis Conclusion	An analytical comparison of benefit vs. risk for a given device or accessory in a given patient population. This may be demonstrated in multiple fashions and can include relative morbidity and/or mortality rates. Acceptability of the risk benefit analysis may be based on regional regulatory requirements, culture, results of any data analysis, and adequacy of supportive documentation. However, in order to accept the residual risk, the benefit must be shown to exceed the risk. If the evidence does not support the conclusion that the benefits outweigh the risks, then the risk will remain unacceptable
Risk Benefit Ratio	Comparison of the overall residual risk category (Low, Moderate or High) to the estimated medical benefits of the device (SIG, IMP, ADV, LOW) expressed as a ratio. An example of an acceptable risk benefit ratio would be Low/SIG. An example of an unacceptable risk benefit ratio would be High/LOW. See the Risk Benefit analysis worksheet (FM-0000457) for more detail.
Risk Control*	Process through which decisions are reached and protective measures are implemented for reducing risk to, or maintaining risks within, specified levels.
Risk Evaluation*	Judgment, on the basis of risk analysis, as to whether an acceptable level of risk has been achieved in a given context based on the current values of society, regulatory considerations and any other factors or values deemed relevant.
Risk Management*	Systematic application of management policies, procedures and practices to the tasks of analyzing, evaluating and controlling risk. Risk Management should start as early as possible in the product's life cycle in order to provide for safety by design. The process covers the entire product life cycle. (*May be abbreviated as **RM***)
Risk Management File*	Sets of records and other documents, not necessarily contiguous that are produced by a risk management process.
Risk Management Plan	A plan prepared in accordance with the Risk Management process. The general Risk Management Plan for Medical Devices is defined in this procedure.
Risk Management	A document that summarizes what was done in the risk

Term	Description
Report (RMR)	management process and that facilitates the assessment of the completeness of the process. (The RM Report is a document type within the electronic document control system and will be stored within this system. See PR-0000001, PR-0000002. Each revision of the report is submitted for approval within the electronic document control system as per PR-0000001 & PR-0000002.) Each RMR will have a discrete document number with a revision number assigned to it (i.e. RMR-000000X, V1) and will be referenced in the DHF/CHF or eDHF and in the Product Quality Plan. The RM Report is a living document and follows the product throughout its entire life cycle, being updated accordingly, with each update creating a new revision # to the document.
Safety*	Freedom from unacceptable risk.
Severity*	Measure of the possible consequences of a hazard
Verification*	Confirmation by examination and provision of objective evidence that specified requirements have been fulfilled

4 Roles and Responsibilities

Functional Group or Responsible Party	Area of Responsibility
Management	WWVP of Regulatory Affairs/Quality Assurance is responsible for the Medical Device Risk Management Program. The WWVP of Clinical/Medical Affairs and the WWVP of RA/QA (or their designees) will approve the RM report for devices in which the Overall Residual Risk Level was deemed to be High, but for which the Benefits outweigh the Risk, as shown through an appropriate Risk Benefit Analysis. For more information on Management responsibility please refer to PL-0000001, The Ethicon Franchise Quality Manual.
Worldwide Quality Engineering (WWQE): DQE	Will assume leadership in the execution, **or will request/ensure execution by other parties as appropriate,** for all Risk Management Activities, to include: Hazard Identification Estimation of risks for each hazard Completion of aFMEA and dFMEA or other appropriate risk analysis tool Risk Evaluation Risk reduction Option analysis Implementation and verification of risk control measures

	Residual Risk evaluation Risk Benefit analysis Assessment for generation of additional hazards when risk control measures are implemented Assessment of overall residual risk Complete appropriate components of the RM plan which supplement this procedure. Create the RM Report Ensure the RM file is complete Update, as required, the aFMEA and dFMEA documents in Ethicon's electronic document management system. Maintain any other Risk analysis documentation accordingly. Review post launch product complaint information at specified intervals to assess adequacy of RM activities.
Project Leader	Will obtain and allocate resources to allow for completion of risk management activities conducted within either the product development or design change process. Is responsible for ensuring that Risk Management is an integral part of the Design Control Project Plan.
Medical Director	Will assist in estimation of severity for each harm that is associated with an identified hazard or hazardous situation. Will, as deemed necessary, assist in generating a procedural process map of the overall surgical procedure (from patient's entering site of use through patient's leaving site of use) as required. If the residual risk assessment indicates the need, the appropriate Medical Director will coordinate/direct the execution of a risk benefit analysis. Assist in assessing the combined impact of all residual risk as per clause 7 of the ISO Standard 14971. **Note:** MD may conclude that risks are not outweighed by benefits, thereby deeming the risk unacceptable. **Note:** The MD may select a designee with relevant clinical experience in the event that the Medical Director does not have adequate experience in a particular clinical application or procedure.
Clinical Affairs	Will review the results of risk management

	activities prior to development of clinical trial protocols to ensure that all pre-requisite requirements have been met. As applicable, during Hazard Identification will assist in providing results of review of FDA and/or other sources of data for information concerning performance or safety issues for products similar in design, application or use.
Worldwide Customer Quality (WCQ)	Will participate as needed in risk analysis activities (e.g. Will provide results of a review of ETHICON's customer complaint data as it relates to products that are similar in design, application or use during the hazards Identification process). After completion of the risk analysis process and prior to product launch will ensure that all anticipated failure modes (as are provided by the Design Quality Engineer) are loaded into the appropriate Complaint Management Database as complaint categories. In the post-launch period will ensure that any new failure modes that are identified via the Risk Management Process are loaded into the appropriate Complaint Management Database as complaint categories. Will advise the DQE when a new complaint category *may* be required. Will maintain post market complaint data to allow for applicable review of the post market experience Will advise management of any actionable complaint trends accordingly.
Product Development Team (Or Designees)	Participate as needed in completion of risk analysis, risk evaluation and risk control activities.
Engineering and/or Process Development	Assist as needed in completing FMEA's or other risk analysis activities.
Independent observer	Will function as per PR800-011 & -012
Risk Manager	Will maintain the Risk Management Process and Procedure
Supplier Quality Management: SQE	For **externally** manufactured products, will ensure the execution of: Completion of external manufacturing process related risk analysis. Will maintain an up to date copy of external pFMEA's. Will obtain up to date copies of any other risk analysis documentation.

Manufacturing QA: MQE	For **internally** manufactured products, will assume leadership in the execution of, or will request execution by other parties as appropriate: Completion of risk analysis as it relates to the internal manufacturing process environment (e.g. pFMEA). Will update, as required, the pFMEA in Ethicon's electronic document management system, or will maintain up to date versions of any other risk analysis tools used.

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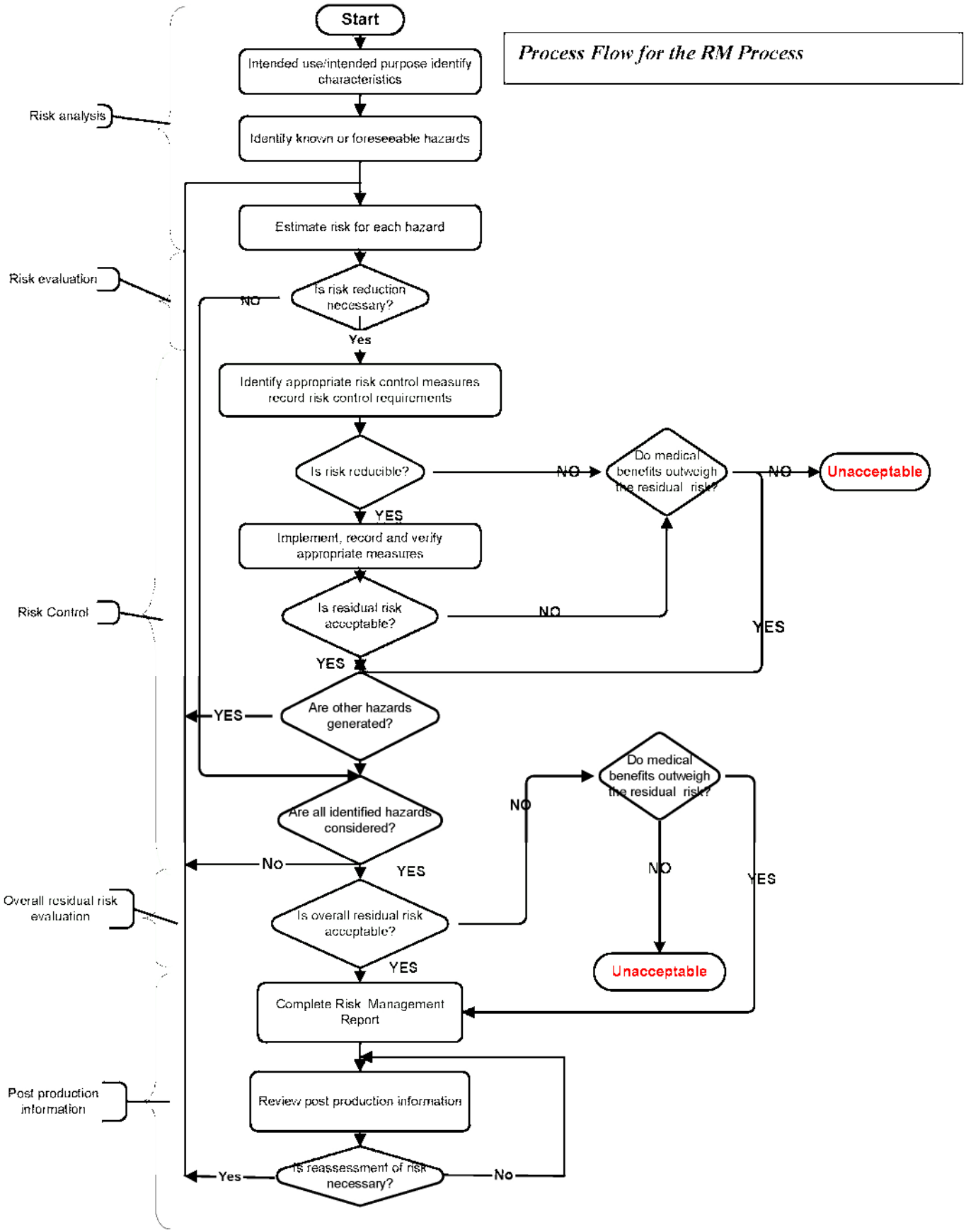


5 Procedure

5.1 Requirements

The execution of the Risk Management Process requires individuals who are trained in the techniques of Risk Management. Combined qualifications of essential personnel involved in the process will also include knowledge about:

How the device is constructed

How the device works

How the device is intended, or likely to be used

How abuse may occur as well as the consequences of misuse

How to apply the risk management process, and

How the device may produce health benefits and/or health risks in general or specific patient populations

5.2 Instructions

Step 1 Risk Management Plan Creation The Risk Management Plan for each device is as per PR602-003. The version of the Company Procedure for Device Design Risk Management, which is in effect at the time of Initiation of the Hazard Identification process, will be considered as part of the Risk Management Plan for that device. This should be noted in the plan.

Activity	Responsible
• Create the Risk management Plan as per the requirements below. • PR602-003 describes a generic Risk Management plan for medical devices. Therefore, a specific RM plan may refer to this procedure for any of the RM Plan elements (see below). Document only the exceptions, specifics or additions accordingly. • All device specific data must be documented in the specific plan (e.g. device name, application, product codes, etc.) • The RM plan will be documented as part of the **Quality Strategy** in the Design and Development Plan or Project Plan as per PR800-011 & -012.	DQE

• RM Plan Elements (the plan will define the following):
  • Scope of the plan
  • Identification of the medical device to include name, purpose, major accessories and components.
  • Identification of the product life cycle phases for which the plan is applicable
  • A verification plan for effectiveness of risk control measures to include methods to be used and location of documentation for verification results.
  • Allocation of responsibilities.
  • Requirements for review of risk management
	DQE

activities • Criteria for risk acceptability • Method to be used for risk analysis • Any guidance documents or performance/process standards to be employed and/or followed (**e.g.: IEC 60601-1-4, AAMI SW68, EN 12442-1, –2. –3**)	
• The RM Plan is approved in conjunction with approval of the Design and Development or Project Plan and is considered to be a component of the Risk Management File. • The RM plan will be documented as part of the Quality Strategy in the Design and Development or Project Plan as per PR800-011 & in the Design Change Plan as per PR800-012.	DQE

Step 2. Risk Analysis

Hazard Identification/ Intended Use and Purpose / Device Characteristics: Hazards may be related to design, manufacturing or user error/user interface.

Note: The risk analysis tools actually used should be in agreement with the method(s) identified on the RM Plan. Refer to OP650-011 (most current version) for instructions on conducting an aFMEA and dFMEA. See PR161-001 (most current version) for instruction on conducting a pFMEA.

Activity	Responsible
Establish a core team with appropriate device and process knowledge as per requirements in section 5.1 of this procedure. The Disciplines to be considered and/or included are (other disciplines not listed may also be included if appropriate- all respective responsibilities should be documented in the RM Plan): • Worldwide Quality Engineering • Medical Affairs • Product Marketing • Development Engineers • World-wide Customer Quality • Process Engineering • Regularity Affairs • Clinical Affairs	DQE and appropriate team members
Identify key characteristics and establish the intended use and purpose. This information should be summarized on the Risk Management Report template (see definitions section for more information on the Risk Management Report Template) and should include: • A definition of physical and functional boundaries, • Complete description of the device(s) and its subsystems, • A description of the environment in which the	DQE and appropriate team members

device will be used, and • A description of the operating conditions to be covered by the risk analysis and assessment.	
Preparation for the Hazard Identification Activity: • Any Preparatory work that is competed should be reviewed and used as input into hazard identification accordingly.	
1. If it is deemed valuable, a procedural process map or product usage map that indicates steps required for use may be created. The Medical Director or designee (designee must possess equal or greater clinical experience and/or expertise) for the appropriate Business Unit should assist in generating the procedural process map for each surgical procedure covered within the scope of application of the device. ○ The process map should show more detail for the portion of the procedure for which the device will be used and should include the anticipated use and effects of concomitant devices or products. ○ The output from this activity, if conducted, will be stored in the Design/Change History File.	DQE/Medical Director with other appropriate team members **Note:** The MD may select a designee with relevant clinical experience in the event that the Medical Director does not have adequate experience in a particular clinical application or procedure.
2. Identify Device Characteristics that could have an impact on safety. Refer to **Annex A** of ISO 14971:2000 for questions that may aid in identifying device characteristic that may impact safety. • A listing of those characteristics that may impact safety should be compiled and included in the Design/Change History File.	
3. Review FDA and other databases for information concerning performance complaints for products similar in design, application or use as the device being considered. ○ Generate a summary. ○ The output from this activity will be stored in the Design/Change History File.	DQE/Clinical Affairs with other appropriate team members
4. World-wide Customer Quality representative will review ETHICON's customer complaint management database for complaints related to any devices that may be similar in design or application and provide a summary of the data. ○ The output from this activity will be stored in the Design/Change History File.	DQE/WCQ with other appropriate team members

5. Development Engineer pre-work may include preparing an overview of the product concept.	DQE/Development Engineer
Identify the hazards and related harms that could result from use, or misuse, of the device. • As a guide, refer to **Annex D** of ISO 14971:2000 for listing of possible hazards. Particular attention should also be paid to hazardous situations as well as hazards. • Document the identified hazards on the Harms/Hazards Summary Table section of the Risk Management Report Template (see definition for more information on Risk Management Report Template). • This listing is updated as additional hazards are identified. • Each hazard identified will be recorded in the Harms/Hazards Summary Table section of the RM Report Template. **Note:** If this activity is being done for the first time in a legacy device (e.g. during design changes, etc.) any previously documented risk documentation may be used as input into completing this step.	DQE and appropriate team members
Rank Severity of Harm. • Following identification of Hazards, rank each hazard's severity using the **Degree of Impact Scale** (see Table 1, Appendix IV) and record it on the Harm/Hazards Summary table section of the Risk Management Report template. • During risk analysis execution, additional hazards/harms with varying severities may also be identified. **Note** that other sections of the Risk Management Report template are not completed at this time. The hazards identified in this activity will be used as input during risk analysis activities.	DQE/Team with other appropriate team members
Risk Estimation • Conduct the risk analysis and estimate risk for each identified hazard as per the risk categorization chart in OP650-011. Risk Estimation will be an input into the Risk evaluation activity.	DQE/team

Step 3. Risk Evaluation

Risk acceptability Decision Guidance

The following will be used as guidance to judge acceptability and make risk acceptability decisions:

Risk may be defined by three levels and using the following guidelines:

- Low/Broadly Acceptable
- Moderate/ALARP
- High/RBA

At a minimum, risks will be reduced to the lowest levels that are reasonably practicable (ALARP). Any individual risks that cannot be lowered to the ALARP or lower range will be judged to be high and will be acceptable only if the anticipated benefits of the product outweigh the product risk.

Activity	Responsible
• For each identified hazard, the risk must be evaluated for the need for further reduction.	DQE/Team (Refer to risk categorization Table in OP650-011)
• If the risk is not at the broadly acceptable level or ALARP level, proceed to Risk Control and Reduction Process.	DQE/Team (Refer to risk categorization Table in OP650-011)
Risk Control/Reduction: **Perform options analysis; Identify Risk Reduction requirements; Implement record and verify control measures** • Perform options analysis (see Appendix III for guidance). • Options analysis may be carried out in conjunction with the execution of the risk analysis and documented as part of the FMEA document (or other risk analysis execution or documentation). • Iterations of the output from this activity will be stored in the Design/Change History File. **Note:** Risk analysis, estimation and control are iterative processes and may be repeated as the design and development process progresses.	DQE/Team
• If the risk cannot be reduced (e.g., because it is not technologically feasible), and the risk is not judged to be in the ALARP or broadly acceptable range, a risk benefit analysis must be conducted (See Risk Benefit analysis worksheet FM-0000457.)	DQE/Team
Verification of Control measures • Two verifications should be completed: 1. Verification that risk control measures were implemented should be part of the design validation process. During execution of design control or design change control, this should be included as part of the design validation effort. 2. All risk reduction or control measures will be verified for effectiveness. The method of verification will be dependant upon the control measure employed. That verification activity and its results will be executed and documented in accordance with the RM plan and will become part of	

the RM file. Continued verification will occur in the postproduction phase via monitoring.	
Assess Residual Risk (See definition section) • Following implementation of control measures, the risk level will be re-assessed and the risk estimation ranking will be updated. Assess this residual risk using the same risk acceptance criteria. • If the residual risk remains at a level that is higher than ALARP and no further reduction is possible, then a Risk Benefit analysis must be conducted as per FM-0000457. • The Completed Risk Benefit Analysis becomes part of the Risk Management File and is stored in the Design History or Change History file.	DQE/Team, MD **Note:** The MD may select a designee with relevant clinical experience in the event that the Medical Director does not have adequate experience in a particular clinical application or procedure.

Step 4 Overall Residual Risk (ORR) Review (See Overall Residual Risk Assessment Method Flow Chart)

Process Overview:
After all risk control measures have been implemented, recorded and verified, the sum, cumulative effect of all of the device's remaining risk will be reviewed in conjunction with the appropriate Medical Director. The sum of all device risk must adhere to the same risk acceptability criteria as previously described. **It is possible that overall residual risk may be unacceptable even if each individual risk was acceptable.**

The results of the overall residual risk review are documented on the RM Report. If the Overall Residual Risk is **High**, a risk benefit analysis must be completed. The appropriate Medical Director will lead this activity, which consists of gathering of appropriate documentation that demonstrates medical benefits of the device.

ORR Process:

Activity	Responsible
• The respective DQE will drive the process and determine who is ultimately involved. The Medical Director (or designee) must be included to establish expected clinical consequences for the overall residual risk.	DQE/MD **Note:** The MD may select a designee with relevant clinical experience in the event that the Medical Director does not have adequate experience in a particular clinical application or procedure.
1: Input: Completed Harms/Hazards Summary Table: • Confirm that all hazards identified during the preliminary hazards identification and that any other hazards identified during execution of the risk analysis (e.g.: completed versions of FMEA's) are listed in the Harms/Hazards Summary Table. • Sort the listing by Harm.	DQE

• Determine the number of failure modes associated with each Hazard and list this number in the summary table in the appropriate column.	
2: Estimate the Frequency of each **Harm** The DQE will work with the Medical Director (or designee) and with any other necessary associates to assess the expected frequency for each of the harms, using **Table 2** (See Appendix IV): The Harm Frequency Estimation Table. • Either the Attribute or the Variable ranking may be used depending on availability of data. • Record the expected frequency for **each of the harms** using the ranking of frequency number (F) from the first column in Table 2 (See Appendix IV). This will be used as input into step 3.	DQE/MD
3: Assess Overall Residual Risk Level • Calculate the sum of all listed expected frequency **rankings (F numbers)**. • This sum is the **overall residual risk score** and should be recorded on the RM Report.	DQE/MD
4: Using **Table 3,** Overall Residual Risk Table (See Appendix IV), assign an overall residual risk level and record on the RM Report.	DQE/MD
5: Select next step based on Overall Residual Risk Level as indicated in Overall Residual Risk Table (Table 3, Appendix IV).	DQE

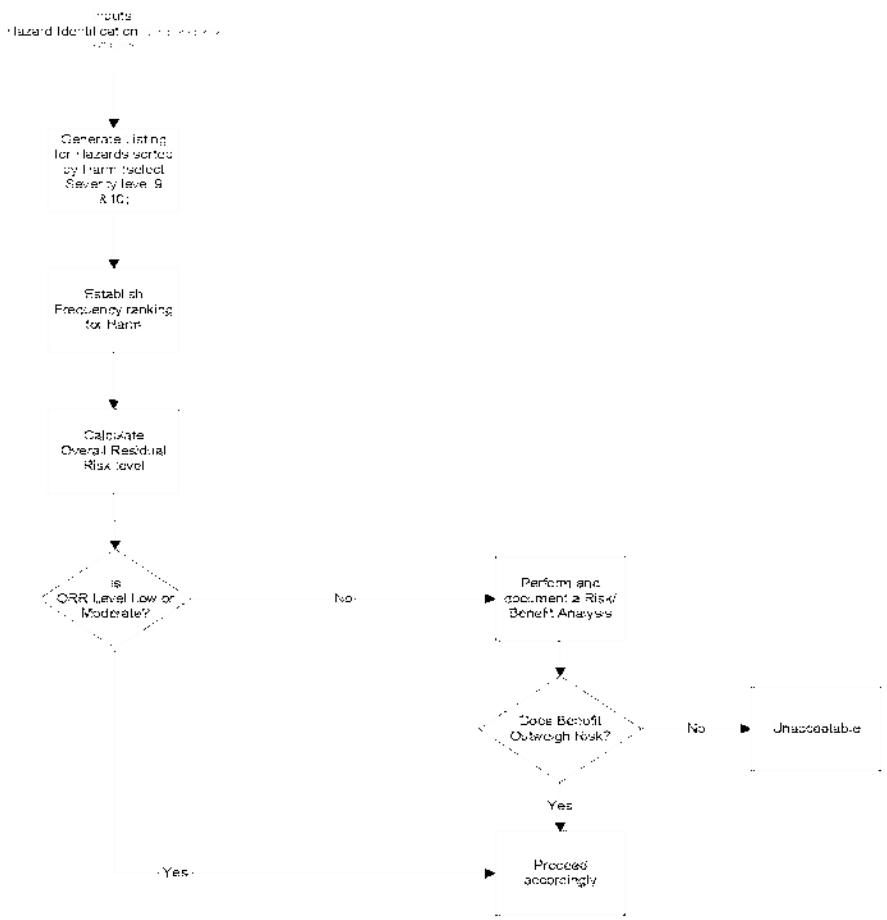
Step 5 Risk Benefit Analysis

In the event that the overall residual risk is deemed **High**, a Risk Benefit Analysis is conducted.

Activity	Responsible
• The Medical Director will perform a risk benefit analysis using Risk Benefit Analysis Worksheet FM-0000457. **Note:** If a risk benefits analysis was already conducted to address any individual risk or for any other purpose, that analysis may be referenced if the scope of the analysis was broad enough to cover all identified aspects of device risk and benefit, and if the scope of the analysis applies to the device in its current state.	MD (MD may select other resources to assist in completing tasks related to this activity.) **Note:** The MD may select a designee with relevant clinical experience in the event that the Medical Director does not have adequate experience in a particular clinical application or procedure.
• Compare benefit vs. risk and document all	MD or designee

supporting documentation used as per the Risk Benefit worksheet (FM-0000457).	
• Assign a Risk Benefit Ratio and draw conclusions as per Risk Benefit analysis worksheet (FM-0000457)	MD or designee
• For products with a High ORR, if the evidence does not support the conclusion that the benefits outweigh the risks, then the risk will become unacceptable. Such an outcome of analysis should be reviewed with the RA/QA BU Head, WW VP of R&D, WW VP of RA/QA or the WW VP of Clinical/Medical Affairs. The results of this evaluation and all the supporting documentation is filed in the Design/Change History File, or e-DHF, and is part of the RM file.	MD/DQE/WWQE Mgr./Project Leader/RAQA BU Head
• Document findings on the RM Report.	QE

Overall Residual Risk Assessment Method Flow Chart



Step 6 Risk Management Report

Activity	Responsible
• Complete the **RM Report** in ETHICON's electronic document control system. A completed RM Report will contain a complete Harms/Hazards Summary Table, Overall Residual Risk Analysis, and any Risk Benefit Analysis outcome (see definition of RM Report for more information). • The appropriate FMEA's (or other risk analysis documentation) must be referenced to allow for traceability of the implementation of all risk control measures for all hazards. • The **initial version** (rev.#1) of the product's Risk Management Report will be completed prior to the execution of a final design review and will be subject to the final design review before it is submitted for approval.	DQE
• Each internal FMEA referenced in the RM Report must reside in Ethicon's electronic document management system (If another Risk analysis tool is used, or in the event that an external FMEA is not contained in the electronic document management system, its location must be referenced in the RM Report).	DQE: aFMEA, dFMEA MQE: pFMEA (internal) SQE: pFMEA (external)
Obtain Appropriate Approvals for the RM Report based on the ORR ranking (see below) **Note**: Approval is gained in accordance with PR-0000001.	DQE
• For **Low** and **Moderate** Level Overall Residual Risk Obtain RM Report approval from: MD, Project Leader (For new Products or projects under Design Change Control) and WWQE Mgr. and proceed.	
• **If the benefits outweigh the risks**, for **High** Level Overall Residual Risk Obtain RM Report approval from: WW VP of Medical Clinical Affairs (or designee), and WW VP of RA/QA (or designee). **Note**: Designees must be at Director level or above.	
• The Approved RM report becomes part of the RM File and will be referenced in the Product Quality Plan and the eDHF, DHF or CHF.	DQE

Step 7 Post Production Activities:

The DQE drives the activity of post-production information review, but may engage resources as appropriate to gather data and subsequently assess it. This is done for the purpose of reassessing the risk management experience and for comparing anticipated potential hazards with actual hazards, which have been shown through use. Possible sources of post launch data include but are not necessarily limited to: product complaints, scientific literature, MDR's and MDV's.

Activity	Responsible
• **Complete the post launch reviews** The first post launch review will be conducted 6 months following initial launch and subsequent reviews will occur every 6 months thereafter for a minimum of 2 years.	DQE- and other resources as needed
• Thereafter, a post launch review of information will be completed at any time that a new (unanticipated) failure mode occurs or if complaint management advises of an actionable trend for a critical/safety related complaint category (Critical Failure Mode- see definition).	DQE- and other resources as needed
• Once either of these occurs, the post launch data review will be monitored again every six months for at least 2 years following the occurrence.	DQE- and other resources as needed
• Compare post launch data to Overall Residual Risk Analysis and applicable FMEA's (or other risk analysis documentation) and any other applicable RM output.	DQE- and other resources as needed
If the comparison indicates: 1. An unanticipated critical failure mode occurred 2. The risk for any hazard/harm has changed because of frequency of occurrence or level of severity or both-or 3. The overall residual risk has increased, the risk analysis and risk management documentation will be updated accordingly. The appropriate team members must be assembled to complete the risk analysis update, implement any necessary risk control measures and re-assess overall residual risk as per this procedure.	DQE/Team
• **Update the RM Report**: the RM Report is updated at the conclusion of each post launch review and will be approved as per PR-0000001. • If no new hazards or failure modes are identified during review, and no change is needed, at a minimum, each version of the RM Report will have an update date, listing of date(s) of post-production review(s), summary explaining no changes were made and name of persons completing the review.	DQE

• **Approvals of <u>updated</u> RM Reports will be as follows:** 1. **Overall Residual Risk remains <u>unchanged, decreases or otherwise remains at or below Moderate</u>: Medical Director, and WWQE Mgr.** 2. **Overall Residual Risk <u>Increases to High:</u> WWVP of RA/QA, and VP of Medical Affairs, or their designees: (Designees must be director level or above).**	
Note: Post Production Reassessment of Risk (Closed Loop risk Management) *In addition to scheduled post launch reviews, risk for the product will be reassessed at any time that:* 1. **New/unanticipated failure modes or harms occur,** 2. **Design changes occur,** 3. **Process changes occur, that necessitate the engagement of the design change control process.** 4. **Frequencies of anticipated failure modes/hazards change significantly (i.e. would cause the risk level to increase)** 5. **If the severity of outcome for any anticipated failure mode/hazard proves to be greater than expected.** 6. **Any event occurs that must be reviewed by the appropriate business unit (BU) Quality Board as per PR551-002 (does not include Product Quality Issues that are not elevated to require a BU Quality Board review).** • If any reassessment of risk indicates an increase in the device risk, then reengagement of the RM process in the **post market period will start at Step 2 of the Risk Management Process: Risk Analysis**, and the Risk Management file components will be updated accordingly. • In the event that the reassessment of risk indicates that the risk has increased to an unacceptable level due to product design, product use or product manufacture issues,	DQE- and other resources as needed

the CAPA process will be engaged to address the cause for the increased risk. Verification of any risk control measures (corrective or preventive actions) may then be executed and documented within the CAPA process. Additional verification will occur with the continued monitoring of postproduction data. The CAPA file reference should be included in the updated RM report in the generic reference documents section of the report.	
• All new documentation becomes part of the RM file and is stored in accordance with established requirements of this plan.	DQE
Note: For **legacy products** still under a 2-year post launch review time period, post market reviews will occur as per previous Risk Management Program, unless an Unanticipated Critical Failure Mode and/or design change involving the need for design validation occurs. In that event, the current Risk Management Plan (as per current version of PR602-003) will be engaged and the existing RM documentation will be updated accordingly.	

Connectivity to Product Complaints

Activity	Responsible
For New Products-Align Complaint Categories to Failure Modes: • Results of the risk analysis (e.g. aFMEA, dFMEA, pFMEA) will be reviewed in order to determine all applicable complaint categories for post market/post launch period. It is possible that multiple hazard/effect parings can contribute to single complaint categories. • It is possible that multiple failure modes may contribute to a single complaint category. Each complaint category must be paired to at least one hazard/effect or failure mode.	DQE/WCQ representative work together to create complaint category listing.
Post Launch tracking of New Complaint Categories: • WCQ will advise DQE of any request for a new complaint category. In the post market/post launch period, if new complaint categories are requested and assigned (as per PR-0000114), the appropriate DQE will assess which hazard/affect or failure mode(s) caused or contributed to the new complaint category. • If the complaint category is associated with an unanticipated failure mode, the risk analysis, risk evaluation and risk	DQE/WCQ

assessment will be updated accordingly.	

5 Appendices

Appendix Number	Appendix Titles
I	Risk Management Process Outputs: Locations
II	Product Development Process Comparison to RM Deliverables
III	Options Analysis Guide
IV	Tables

APPENDIX I: RISK MANAGEMENT PROCESS OUTPUTS: LOCATIONS (NOTE: FOR SPECIFIC RISK MANAGEMENT OUTPUT DOCUMENT REFERENCES, SEE THE PQP IF ONE EXISTS. IN THE EVENT THAT ADDITIONAL OUTPUTS ARE PRODUCED DURING CONTINUED RM ACTIVITIES, ENSURE THAT ANY RELEVANT PQP'S ARE APPROPRIATELY REVIEWED AND/OR UPDATED- SEE PR-0000125)

Document/Output	Location	ISO 14971: 2000 Reference
Risk Mgmt. Plan	PR602-003 current version & Quality Strategy in DHF, eDHF, CHF	3.5
Device characteristic listing.	List will be stored in DHF, eDHF or CHF.	
Hazard Identification	ECCS: RM Report Preliminary Hazard Identification out put in DHF. eDHF or CHF.	4.2, 4.3, 4.4
Risk Analysis	ECCS: for FMEA's; or, if other tools used, DHF; e-DHF, CHF.	4.1
Risk Evaluation Results	ECCS: for FMEA's; or, if other tools used, DHF; e-DHF, CHF.	5
Risk Control Measures	ECCS: for FMEA's; or, if other tools used, DHF; e-DHF, CHF.	6
List of any New Hazards generated by Control Measures	ECCS: RM Report	6.6
Risk Benefit Analysis	ECCS: Outcome in RM Report with the completed Risk Benefit Analysis Worksheet and details in eDHF. CHF. DHF.	6.5
Overall Residual Risk Review and Evaluation	ECCS: RM Report, DHF, e-DHF, CHF	7
Risk Mgmt. Report	ECCS: RM Report, DHF, eDHF, CHF	8
Post Production Information	ECCS: RM Report; DHF, eDHF, CHF	9

APPENDIX II : PRODUCT DEVELOPMENT PROCESS COMPARISON TO RM DELIVERABLES (NOTE: THIS IS A GENERAL GUIDE ONLY)

DESIGN CONTROL PHASE	RISK MANAGEMENT PHASE
Design & Development Planning	RM Plan (Quality Strategy)
Design Input	Preliminary Hazard Identification, Risk estimation
Design Output	Risk analysis Risk Estimation Risk Assessment Risk Control Measures
Design Reviews	Updates on Risk Analysis, Hazards Listings
Design Verification	Verification of Risk Control Measures Update Risk analysis Risk Benefit Analysis (as needed)
Design Validation	Verification of Risk Control Measures Update Risk analysis Risk Benefit Analysis (as needed) Overall Residual Risk Estimation
Design Transfer	RM Report
Post Production	Post Launch Risk Management Reviews

APPENDIX III: OPTIONS ANALYSIS GUIDE

Options analysis guide:

- Any one or all of the options may be used if deemed practicable.
- Options analysis will result in either identification of practical, appropriate control measures in which the risk is reduced or in the need to conduct a risk benefit analysis.
- Options analysis, control measure identification and implementation can be an iterative process. The risk analysis should be updated as these activities occur.

Options for reduction are:

- Practicable design changes that will be implemented as per the design control process as defined in OP800-011 or -012.
- Practicable control/safeguard measures can be established and documented in a control plan.
- New labeling, changes in labeling, changes in Instructions for Use (IFU), addition of warnings in labeling, and/or changes in the user training strategy.

Note: Listing or inclusion within the product labeling regarding residual risk (s) should be considered when drafting the IFU (labeling) content. If residual risks are not included in the product's labeling, a rationale should be documented in the RM report. No medical device is expected to be without some level of risk. However, many of these risks are so low as to be broadly acceptable or so obvious as to require no explicit warning. Such risks may not need any inclusion in the product labeling. (In the event of postproduction options analysis, the labeling content must always be reviewed in light of any new risk information.)

APPENDIX IV: TABLES

Table 1: Degree of Impact Scale for Hazards

RANKING	DEGREE OF IMPACT
9	Harm can be caused but User is **aware** of that Harm as or shortly after it occurs. In some cases, remedial action can be taken to reduce/eliminate long-term impact of Harm at that time.
10	Hazardous without warning. Harm can be caused but User is **unaware** of that Harm occurred at or shortly after it occurs.

Table 2: The Harm Frequency Estimation Table

Guide for using table:

1. Frequency refers to frequency of harm after control measures have been implemented.
2. If sufficient data is available use the variable description column.
3. If insufficient data is available, or if the variable description is not otherwise appropriate, use the attribute description column.
   Assign a Ranking of Frequency (F).

Ranking of Frequency (F)	Attribute Description	Variable Description*
0	Extremely Remote	1/100,000
2	Remote	1/50,000
4	Unlikely	1/10,000
6	Low	1/5,000
8	Rare	1/1,000
10	More than Rare	1/500

*Per number of devices or procedures as dictated by nature of device

Table 3: Overall Residual Risk Table

Overall Residual Risk Score (sum of rankings values-F)	Overall Residual Risk Level	Next Step
0 – 9	Low	Complete RM Report and obtain approval
10-29	Moderate	Complete RM Report and obtain approval
>29	High	Conduct a Risk/Benefit Analysis